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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:
Shigeru NEMOTO

SERIAL NO: 10/691,570 GROUP: 3737

FILED: October 24, 2003 EXAMINER:

FOR: LIQUID INJECTOR WITH APPROPRIATE OPERATING CONDITIONS SET BY SELECTING DISPLAYED IMAGE

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith is a Chinese Office Action (with English Translation) for the Examiner's consideration. The reference(s) cited therein have been previously filed on July 29, 2004.

Respectfully Submitted,

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Text of the Notification of the Second Office Action

After receiving the observations and the amended application documents submitted by the applicant, the examiner continues the examination of the application after reading the above documents and provides the opinions as follows:

The applicant states in the observations that document 1 differs from claim 1 of the present invention in that "displaying and selecting the schematic image of a plurality of body sections of the human body and schematic images of a plurality of regions to be imaged of the human body" has not been disclosed. However, the examiner thinks that the user interface display disclosed in Document 1 (US2003/0018252A1) further includes selectable input receptors activitable by a user to select different injection procedures such as for the study of the left coronary, the right coronary or the left ventricle and aorta portion of a human anatomy (refer to paragraph 22 of the specification of Document 1), the selectable input receptors may also be used to select different injection parameters or to select either fixed rate or variable rate injection modes of operation. In addition, document 1 also discloses that said means further includes "select injection" keys indicated as LCA (left coronary artery) and RCA (right coronary artery) for selecting different anatomy, after the above input keys are selected, the default parameter values for the selected type is displayed (refer to paragraph 0180 of the specification of Document 1). Thus, Document 1 also discloses a region displaying means and a region selecting means for the user to select different anatomy regions and to accept an input action of user to select the displayed regions. Although document 1 does not clearly describe what said means displays and selects is text description or image information of the regions to be imaged, whatever the means displays, both may easily and reliably set optimized operating conditions of injecting a contrast medium by displaying the above information, the operator is not required to perform complicated process to input data such as injection rate, so as to avoid the possible mistake during inputting data, and it is a common function of the imaging means in the technical field to display section

images. Therefore, it is easy to obtain the technical solution of claim 1 by combining the common selection on the basis of Document 1, thus claim 1 does not inventiveness, its dependent claims 2-36 do not possess inventiveness. The reasons why claims 1-36 do not possess inventiveness as required by the provision of paragraph 3, Article 22 of the Patent Law are described in more detail as below.

1. Claims 1-36 do not possess inventiveness as required by the provision of paragraph 3, Article 22 of the Patent Law.

Claim 1 seeks protection for a liquid injector for injecting at least a contrast medium into a subject whose fluoroscopic image is to be captured by an imaging diagnostic apparatus. Document 1(2003/0018252A1), however, discloses an angiographic injector for injecting a contrast medium into a subject (refer to Parts [0020] to [0022], [0179] to [0202] and Figures 1, 11A and 31). The injector comprises: a liquid injection mechanism for injecting a contrast medium into a subject; a condition storage means for storing data of operating conditions of the liquid injection mechanism; an input means for entering the patient value prior a injection or for selecting different anatomy such as for the study of the left coronary, the right coronary, the left ventricle and aorta portion of a human anatomy according to input data selected by user; a user interface display means for receiving an input signal and for displaying information to users; a driving means for reading operating data and for driving a liquid injection according to data that has been read; a computer for controlling the driving means so as to control the liquid injection.

Document 1 differs from claim 1 in that (1) section display means for displaying the schematic images of the body sections in the shape of a human body; (2) region displaying means for displaying the schematic image of at least one of the regions to be imaged in relation to the selected schematic image of the body section; region input means for accepting an input action to select the displayed schematic image of at least one of said regions to be imaged.

As for the distinguishing feature (1), since the angiographic liquid injector of Document 1 is used together with the imaging means such as CT and X rays, the region displaying means and the section display means that display the schematic

images of the body sections in the shape of a human body are conventional components of said imaging means, employing the region displaying means and the section display means of the imaging means in the means of injecting a contrast medium is a common selection in the art.

As for the distinguishing feature (2), Document 1 also discloses that the computer also provides data for displaying real time output parameters related to the injection procedure of a system such as an accumulated injection volume or the instantaneous flow rate occurring during an injection, and the user interface display also includes selectable input receptors activatable by a user to select different injection procedures such as for the study of the left coronary, the right coronary or the left ventricle and aorta portion of a human anatomy (refer to paragraph [0022] of the specification of document 1), said selectable input receptors may also be used to select different injection parameters or injection modes. In addition, document 1 also discloses that said means further includes "select injection" keys indicated as LCA (left coronary artery), RCA (right coronary artery) for selecting different anatomy, after the above input keys are selected, the default parameter values for the selected type is displayed (refer to paragraph 0180 of the specification of Document 1). Thus, Document 1 also discloses a region displaying means and a region selecting means for the user to select different anatomy region and to accept an input action of user to select the displayed regions. Although document 1 does not clearly describe what said means displays and selects is text description or image information of the regions to be imaged, whatever the means displays, both can easily and reliably set optimized operating conditions of injecting a contrast medium, the operator is not required to perform complicated process to input data such as injection rate, so as to avoid the possible mistake when inputting these data, and it is a common function of the imaging apparatus in the technical field to display section images. Therefore, it is easy to obtain the technical solution of claim 1 by combining the common selections on the basis of Document 1, thus claim 1 does not inventiveness.

As for the dependent claim 2, since document 1 also discloses that the liquid injector includes a medium injection mechanism for injecting a contrast medium and

it can also store data of operating conditions, wherein, said condition storage means is configured to store data of operating conditions so as to set operating conditions corresponding to the injection mechanism in relation to each imaged region, and the injection control means controls the injection mechanism according to read data (refer to paragraph [0020] to [0022] of Document 1). Although document 1 adopts only one injection mechanism, the injection mechanism can not only inject the contrast medium, but also inject a saline solution or other solutions, further, adopting a solution injection mechanism for injecting the saline solution and a injection mechanism for injecting the contrast medium is also a means commonly used in the art, claim 2 does not possess inventiveness.

The additional technical features of dependent claims 3-4 have been disclosed in Document 1. The condition storage means of Document 1 includes the means for storing data of multiple operating modes including the adjusting for injection rate of the contrast medium, the controlling for the operating rate of the injection mechanism and the contrast of the radiography image (refer to paragraphs [0020] to [0022], and [0179] to [0181]). Therefore, if the claim referred to does not possess inventiveness, said claims do not possess inventiveness.

As for claims 5-8 and 10-11, since document 1 discloses that the liquid injection means includes the body display means for displaying body item (e.g., the weight) of the human body; the body input means for accepting the related body item and the operation adjusting means for adjusting operating conditions in accordance with the entered data of body items; the condition storage means includes the means for storing the operating conditions for the corresponding body items, and the operation reading means includes the means for reading the data of the operating conditions corresponding to the selected body items (refer to paragraphs [0020] to [0022] and [0179] to [0181]). It can be seen that the additional technical features of claims 5-8 have been disclosed in document 1. Therefore, dependent claims 5-8 do not possess inventiveness.

As for dependent claim 9, since it is a conventional technology that data is entered on-line from an external database, if the claim which refers to does not

possess inventiveness, dependent claim 9 does not possess inventiveness.

The additional technical features of claims 12-18 have been disclosed in document 1 (refer to paragraphs [0179] to [0181] and [0185] to [0206]). Therefore, if the claim referred to does not possess inventiveness, dependent claims 12-18 do not possess inventiveness.

The additional technical features of claims 12-18 further define the imaging apparatus and the operation adjusting means. Since different types of the imaging apparatus can be used together with the liquid injection means in an injection and the imaging apparatus commonly used in the art includes the imaging storage means, the imaging display means, the imaging input means and the imaging reading means, and changing the operating conditions according to the read data is a conventional technique adopted by those skilled in the art. Therefore, if claim referred to does not possess inventiveness, dependent claims 19-24 do not possess inventiveness.

As for dependent claims 25-31, document 1 discloses that two computers are employed to control the system and store data (refer to paragraphs [0155] to [0156]). A person skilled in the art knows clearly that a computer includes a medium input means such as an optical driver and a floppy driver, and updates data stored in the condition storage means through the read data of operating conditions. Since using an external storage medium to store data of imaging items and reading data from a external storage medium by a data reading means are the conventional selections for those skilled in the art, and inputting data of operating conditions on-line from an external storage medium and updating data of operating conditions stored in the condition storage means by use of the input data are the conventional techniques adopted in the art. Therefore, if the claim referred to does not possess inventiveness, dependent claims 25-30 do not possess inventiveness.

The additional technical features of dependent claims 32-36 have been disclosed in document 1 (refer to paragraphs [0020] to [0022] and [0179] to [0202] and figures 1, 11A, 31). Therefore, if the claim referred to does not possess inventiveness, dependent claims 32-36 do not possess inventiveness.

Based on the above reasons, claims 1-36 of the present application do not possess

inventiveness, and no substantive matter for which a patent right might be granted is recorded in the specification. If the applicant does not state the convincing reasons within two months, the application shall be rejected according to Article 53 of the Implementing Regulations of the Patent Law.

OIJP031759

中华人民共和国国家知识产权局

100029 北京市朝阳区裕民路12号中国国际科技会展中心A1210号 北京银龙知识产权代理有限公司 郭晓东	发文日
申请号：2003101153985	
申请人：株式会社根本杏林堂	
发明名称：通过选择显示图像设定适当的操作条件的液体注射装置	

专利 2007.5.25 发文

专利 2007.5.25 发文

第 2 次审查意见通知书

1. ☑审查员已收到申请人于2005年12月21日提交的意见陈述书，在此基础上审查员对上述专利申请继续进行实质审查。

☐根据国家知识产权局专利复审委员会于　　年　月　日作出的复审决定，审查员对上述专利申请继续实质审查。

☐_____

2. ☐申请人于　　年　月　日提交的修改文件，不符合专利法实施细则第51条第3款的规定。

3. 继续审查是针对下述申请文件进行的：

☐上述意见陈述书中所附的经修改的申请文件。

☑前次审查意见通知书所针对的申请文件以及上述意见陈述书中所附的经修改的申请文件替换页。

☐前次审查意见通知书所针对的申请文件。

☐上述复审决定所确定的申请文件。

☐_____

4. ☑本通知书未引用新的对比文件。

☐本通知书引用下述对比文件（其编号续前，并在今后的审查过程中继续沿用）：

编号　　文件号或名称　　公开日期（或抵触申请的申请日）

5. 审查的结论性意见：

☐关于说明书：

☐申请的内容属于专利法第5条规定的不授予专利权的范围。

☐说明书不符合专利法第26条第3款的规定。

☐说明书的修改不符合专利法第33条的规定。

☐说明书的撰写不符合专利法实施细则第18条的规定。

☐_____

☑关于权利要求书：

☐权利要求_____不具备专利法第22条第2款规定的新颖性。

☑权利要求 1-36 不具备专利法第22条第3款规定的创造性。

☐权利要求_____不具备专利法第22条第4款规定的实用性。

☐权利要求_____属于专利法第25条规定的不授予专利权的范围。

☐权利要求_____不符合专利法第26条第4款的规定。

☐权利要求_____不符合专利法第31条第1款的规定。

☐权利要求_____的修改不符合专利法第33条的规定。

☐权利要求_____不符合专利法实施细则第2条第1款的规定。

☐权利要求_____不符合专利法实施细则第13条第1款的规定。

☐权利要求_____不符合专利法实施细则第20条的规定。

中华人民共和国国家知识产权局 专利审查业务章 58

☐权利要求_____不符合专利法实施细则第 21 条的规定。
☐权利要求_____不符合专利法实施细则第 22 条的规定。
☐权利要求_____不符合专利法实施细则第 23 条的规定。
☐_____
☐分案的申请不符合专利法实施细则第 43 条第 1 款的规定。
上述结论性意见的具体分析见本通知书的正文部分。

6. 基于上述结论性意见，审查员认为：
☐申请人应按照通知书正文部分提出的要求，对申请文件进行修改。
☐申请人应在意见陈述书中论述其专利申请可以被授予专利权的理由，并对通知书正文部分中指出的不符合规定之处进行修改，否则将不能授予专利权。
☑专利申请中没有可以被授予专利权的实质性内容，如果申请人没有陈述理由或者陈述理由不充分，其申请将被驳回。
☐_____

7. 申请人应注意下述事项：
(1) 根据专利法第 37 条的规定，申请人应在收到本通知书之日起的贰个月内陈述意见，如果申请人无正当理由逾期不答复，其申请将被视为撤回。
(2) 申请人对其申请的修改应符合专利法第 33 条和实施细则第 51 条的规定，修改文本应一式两份，其格式应符合审查指南的有关规定。
(3) 申请人的意见陈述书和/或修改文本应邮寄或递交国家知识产权局专利局受理处，凡未邮寄或递交给受理处的文件不具备法律效力。
(4) 未经预约，申请人和/或代理人不得前来国家知识产权局专利局与审查员举行会晤。

8. 本通知书正文部分共有 4 页，并附有下述附件：
☐引用的对比文件的复印件共_____份_____页。
☐_____

审查员：许敏(5511)　　审查部门　光电技术审查部
2007 年 5 月 10 日

回函请寄：100088 北京市海淀区蓟门桥西土城路 6 号　国家知识产权局专利局受理处收
（注：凡寄给审查员个人的信函不具有法律效力）

第二次审查意见通知书正文

审查员收到申请人于 2005 年 12 月 21 日提交的针对第一次审查意见通知书的修改文件和意见陈述书，经审查，审查意见如下：

申请人在意见陈述书中陈述了对比文件 1 与本发明权利要求 1 的区别在于并未揭示“显示和选择人体的多个身体断面的示意图像和人体的多个将被成像的多个区域的示意图像”，但审查员认为：在对比文件 1（US2003/0018252A1）中公开了该装置的用户界面显示还包括由用户激发的用户界面接收器，用户可通过该界面接收器选择不同的注射过程，如用于左冠状动脉，右冠状动脉、左心室等人体的解剖结构（参见对比文件 1 说明书第【0022】）段，该选择性输入接收器还可用于显示不同的注射参数或注射模式。另外，对比文件 1 中还公开了该装置还包括“选择注射键 LCA（左冠状动脉），RCA（右冠状动脉）等输入键，用于供用户选择不同的解剖结构，在选择上述输入键后，就会显示所选择类型的缺省的参数（参见对比文件 1 说明书第【0180】段），由此可见，对比文件 1 中也提供了一种区域显示装置和区域选择装置，用于供用户选择不同的解剖区域和接受用户的输入动作以便选择显示的区域。虽然对比文件 1 中没有明确描述所述装置显示和选择的是成像区域的文字描述还是图像信息，但无论显示的是成像区域的文字描述还是图像信息，其作用都是相同的，都能够通过显示上述信息而容易可靠地设置注射造影剂的优化操作条件，不需要操作者执行复杂的程序来输入诸如注射速度等数据，从而能够避免操作者在输入这些数据方面可能产生的错误，而且显示断层图像本身也是本领域中的成像装置具有的常规功能。因此，在对比文件 1 的基础上结合本领域的常规选择容易得到权利要求 1 的技术方案，因此权利要求 1 不具备创造性，其从属权利要求 2-36 也不具备创造性。下面对权利要求 1-36 不具备专利法第 22 条第 3 款规定的创造性的理由进行具体说明。

一.权利要求 1—36 不具备专利法第 22 条第 3 款规定的创造性。

独立权利要求 1 请求保护一种将至少一种造影剂注射到由成像诊断设备捕获其荧光图像的主体中的液体注射装置，对比文件 1（US2003/0018252A1）公

开了一种将造影剂注射到主体中的血管造影液体注射装置（参见对比文件 1 第【0020】－【0022】部分，第【0179】－【0202】部分，附图 1，11A,31），该装置包括一个液体注射机构，用于将造影剂注射到主体中；条件存储装置，用于存储液体注射机构的操作条件数据；输入装置，用于在注射前输入患者数据或根据用户选择的输入数据选择不同的解剖结构，如左冠状动脉，右冠状动脉、左心室等人体的解剖结构；用户界面显示装置，用于接收输入信号并向用户显示信息；用于读取操作数据用于驱动装置，用于根据已经读取的数据驱动液体注射；计算机，用于控制驱动装置从而控制液体注射。

对比文件 1 与权利要求 1 的区别在于：（1）断面显示装置，用于以人体形状显示身体端面的示意图象；（2）区域显示装置，用于相对选择的身体断面的示意图象，显示至少一个将被成像的区域的示意图象；区域输入装置，用于接受一个输入动作以便选择显示的至少一个将被成像的区域的示意图像。

对于区别特征（1），由于对比文件 1 中的血管造影液体注射装置是与 CT、X 线等成像装置结合使用的，而用于以人体形状显示人体横切面的示意图象的断面显示装置是上述成像装置的常规部件，在注射造影剂装置中结合成像装置的人体断层面显示装置属于本领域的常规选择；

对于区别特征（2），对比文件 1 中还公开了计算机也提供用于显示与注射过程相关的实时输出参数的数据，例如累积注射体积或流速，并且用户界面显示还包括由用户激发的用户界面接收器，用户可通过该界面接收器选择不同的注射过程，如用于左冠状动脉，右冠状动脉、左心室等人体的解剖结构（参见对比文件 1 说明书第【0022】）段，该选择性输入接收器还可用于显示不同的注射参数或注射模式。另外，对比文件 1 中还公开了该装置还包括“选择注射键 LCA（左冠状动脉），RCA（右冠状动脉）等输入键，用于供用户选择不同的解剖结构，在选择上述输入键后，就会显示所选择类型的缺省的参数（参见对比文件 1 说明书第【0180】段），由此可见，对比文件 1 中也提供了一种区域显示装置和区域选择装置，用于供用户选择不同的解剖区域和接受用户的输入动作以便选择显示的区域。虽然对比文件 1 中没有明确描述该显示装置和选择装置所显示和选择的是成像区域的文字描述还是图像信息，但无论显示的是成像区域的文字描述还是图像信息，其作用都是相同的，都能够通过显示上述信息而容易可靠地设置注射造影剂的优化操作条件，不需要操作者执行复杂

的程序来输入诸如注射速度等数据，从而能够避免操作者在输入这些数据方面可能产生的错误，而且显示断层图像本身也是本领域中的成像装置具有的常规功能。因此，在对比文件 1 的基础上结合本领域的常规选择容易得到权利要求 1 的技术方案，因此权利要求 1 不具备创造性。

对于从属权利要求 2，由于对比文件 1 还公开了所述液体注射机构包括用于注射造影剂的介质注射机构，其也可以用于存储操作条件数据，所述条件存储装置用于存储操作条件的数据，以便相对于每一个成像区域设置注射机构对应的操作条件，注射控制装置包括用于根据读取的数据控制注射机构（参见对比文件 1 第【0020】－【0022】部分）。虽然对比文件 1 中只采用了一个注射机构，但该注射机构既可以注射造影剂，也可以注射盐溶液和其它溶液，而且，分别采用一个用于注射盐溶液的溶液注射机构和注射造影剂的注射机构也是本领域经常采用的技术手段，因此从属权利要求 2 不具备创造性。

从属权利要求 3－4 的附加技术特征在对比文件 1 中已公开，对比文件 1 中的条件存储装置包括用于存储多种操作模式的数据的装置，这些模式包括调整注射造影剂的注射速度和控制注射机构的操作速度和造影图象的对比度（参见对比文件 1 第【0020】－【0022】部分，第【0179】－【0181】部分）。因此在其引用的权利要求不具备创造性时，上述权利要求也不具备创造性。

对于从属权利要求 5－8，10－11，由于对比文件 1 公开了该液体注射装置包括显示人体的身体项目（如体重）的身体显示装置；接受有关身体项目的身体输入装置和根据选择的身体项目调整操作条件的操作调整装置；条件存储装置包括存储身体项目对应的操作条件，操作读取装置包括用于相对于选择的身体项目读取操作条件的数据的装置（参见对比文件 1 第【0020】－【0022】部分，第【0179】－【0181】部分），由此可见，从属权利要求 5－8 的附加技术特征在对比文件 1 中已公开，因此，从属权利要求 5－8 不具备创造性。

对于从属权利要求 9，由于在线地从外部数据库设备中输入数据属于本领域常用技术手段，因此在其引用的权利要求不具备创造性时，从属权利要求 9 不具备创造性。

从属权利要求 12－18 的附加技术特征在对比文件 1 中已公开（参见对比文件 1 第【0179】－【0181】部分，第【0185】－【0206】部分），因此在其引用的权利要求不具备创造性时，从属权利要求 12－18 不具备创造性。

从属权利要求 19－24 的附加技术特征对成像设备和操作调整装置进行了进一步的限定，由于在血管造影中可以使用不同类型的成像装置与液体注射装置结合使用，本领域通常使用的成像装置都包括成像存储装置、显示装置、成像输入装置、成像读取装置、并且根据读取的成像项目的数据调整操作条件也是本领域技术人员经常采用的技术手段，因此在其引用的权利要求不具备创造性时，从属权利要求 19－24 不具备创造性。

对于从属权利要求 25－31，对比文件 1 中公开了利用两台计算机对系统进行控制并存储数据（参见对比文件 1 第【0155】－【0156】部分），而本领域技术人员熟知计算机中包括诸如光驱、软驱等媒介装入装置，并利用读取的操作条件数据更新存储在条件存储装置中的数据，由于使用存储成像项目数据的外部存储介质并通过数据读取装置从外部存储介质中读取数据是本领域技术人员的常规选择，而通过在线方式从外部存储介质输入操作条件数据并利用输入的数据更新存储在条件存储装置中的操作条件数据也属于本领域经常采用的技术手段，因此在其引用的权利要求不具备创造性时，从属权利要求 25－30 也不具备创造性。

从属权利要求 32－36 的附加技术特征在对比文件 1 中已公开（参见对比文件 1 第【0020】－【0022】部分，第【0179】－【0202】部分，附图 1，11A,31），因此在其引用的权利要求不具备创造性时，上述权利要求也不具备创造性。

基于上述理由，本申请的权利要求 1－36 不具备创造性，并且说明书中也没有可以授予专利权的实质性内容，如果申请人在指定的 2 个月的期限内不能提出具有说服性的理由，审查员将依据实施细则第 53 条驳回本申请。